

REMARKS

In the Office Action mailed May 25, 2010, the Examiner rejected claims 11 and 21-39. By way of the foregoing amendments and the markings to show changes. No amendments are presented herewith and claims 11 and 21-39 remain pending. The foregoing amendments are taken in the interest of expediting prosecution and there is no intention of surrendering any range of equivalents to which Applicant would otherwise be entitled in view of the prior art.

Further, by the present amendment, it does not follow that the amended claims have become so perfect in their description that no one could devise an equivalent. After amendment, as before, limitations in the ability to describe the present invention in language in the patent claims naturally prevent the Applicants from capturing every nuance of the invention or describing with complete precision the range of its novelty or every possible equivalent. See, Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 62 USPQ2d 1705 (2002). Accordingly, the foregoing amendments are made specifically in the interest of expediting prosecution and there is no intention of surrendering any range of equivalents to which Applicants would otherwise be entitled.

Rejections under 35 U.S.C. § 103

The office action rejected claims 11 and 21, 24-26, 32, 33, and 38 as being unpatentable over Smedley (7,163,543) in combination with Peyman (7,354,574). The office action rejected claims 22, 27, and 28 as being unpatentable over Smedley and Peyman and further in view of Bardenstein (4,743,255). Claims 23, 29-31, 34-37, and 39 as being unpatentable over Smedley and Peyman and further in view of Wong (6,692,759) as applied to claims 23, 29-30, 36, and over the combination of Smedley, Peyman, and Bardenstein futher in view of Wong as applied to claims 31, 34-35, 37, and 39. "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1790).

a) Paragraph 4

The office action rejected claims 11 and 21, 24-26, 32, 33, and 38 as being unpatentable over Smedley (7,163,543) in combination with Peyman (7,354,574).

i. Lack of Fact Findings

The office action alleges that claim 11 is obvious in view of Smedley and Peyman. The office action; however, has failed to show where each and every element of the device in claim 11 is taught by the references of record. The office action alleges that claim 11 is obvious in view of MPEP § 2144.04(IV)(B) and *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966). Applicants respectfully disagree that claim 11 is obvious in view of Smedley and Peyman in view of *Dailey*. In *Dailey*, the court discusses two prior art references for a nursing container. The court states that, "one of ordinary skill in the art would find it obvious to use the slit nipple of Blanchett in the collapsible container of Matzen in order to achieve intermittent flow responsive to sucking." The court after performing this fact finding and presenting facts as to where every element of the claim was taught by a prior art reference concludes that it would have been obvious for one skilled in the art to have combined Blanchett and Matzen to arrive at the claimed invention. The office action has **not** performed the fact finding that the court performed in *Dailey*. The office action has not presented any facts as to where any reference teaches "a lumen section that extends into the eye and wraps generally circularly around the cornea." Without performing the required fact finding the office action cannot come to the conclusion that claim 11 is obvious. Moreover, ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness").... *KSR International co. v. Teleflex, Inc.*, 82 U.S.P.Q.2d 1385, 1396 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)).

The office action alleges that Smedley in combination with Peyman teaches claims 25; however, the office action did not point to any facts in either reference showing where they teach claim 25. Specifically claims 25 states, "wherein the first end when implanted is located in the anterior chamber of the eye or in the pars plana portion of the eye." Applicants do not believe that the office action has presented a proper *prima facie* obviousness rejection of this claim and its dependents and respectfully request that the rejection be withdrawn and the claim allowed.

The office action alleges that claims 24 and 32-34 are taught by Smedley; however, the office action has failed to present any facts as to where Smedley teaches a coating that covers the openings in the lumen. The office action has the burden to show where every element of the claims is taught either expressly or inherently by the references of record. A mere conclusory statement does not create a proper *prima facie* obviousness rejection and Applicants respectfully request that the rejection be withdrawn. ("[R]ejections on obviousness grounds cannot be

sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness")..... KSR International co. v. Teleflex, Inc., 82 U.S.P.Q.2d 1385, 1396 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006)).

ii. Lack of Evidentiary Support for the Fact Findings

The office action alleges that Smedley teaches claim 38; however, Applicants do not believe that the facts as alleged is supported by the evidence found in Smedley. Claim 38 states, "wherein the device includes a focal surrounding element that can be altered to shrink and constrict the lumen." The office action cites col. 9, lines 36-46 which states,

In modified embodiments, the flow-restricting member 72 (FIG. 5) may be situated in any location within the device 31 and/or 31A such that blood flow is restricted from retrograde motion. More than one flow-restricting member 72 may also be efficaciously used, as needed or desired. The flow-restricting member 72 may, in some embodiments, be a filter made of a material selected from the following filter materials: expanded polytetrafluoroethylene, cellulose, ceramic, glass, Nylon, plastic, and fluorinated material such as polyvinylidene fluoride ("PVDF") (trade name: Kynar, by DuPont), and combinations thereof.

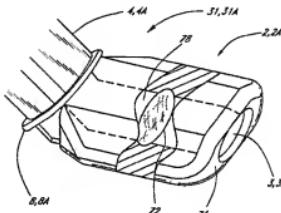


FIG. 5

Foremost, this passage states that the "flow restricting member 72 (FIG. 5) may be situated in any location within the device." (emphasis added) Claim 38 claims "a focal surrounding element that can be altered to shrink and constrict the lumen." Applicants do not believe that the flow restricting device will be able to shrink and constrict the lumen from the inside of the lumen. Furthermore, if the flow-restricting member shrinks Applicants do not believe that it will be able to "restrict[] retrograde motion [of blood flow]." If the flow restrictor is no longer able to restrict retrograde motion of blood flow then the proposed modification will render the prior art unsatisfactory for its intended purpose in violation of MPEP 2143.01. Therefore, Applicants do not believe that a proper *prima facie* obviousness rejection has been presented by the office action, and Applicants respectfully request that the rejection be withdrawn.

b) Paragraph 5

The office action rejected claims 22, 27, and 28 as being unpatentable over Smedley and Peyman and further in view of Bardenstein (4,743,255). The office action has failed to present a prima facie obviousness rejection of the preceding claims to which claims 22, 27, and 28 depend. The office action has not presented any facts or evidence showing where Bardenstein cures any of the defects discussed regarding those claims. Therefore, Applicants do not believe that a proper prima facie obviousness rejection has been presented as to these claims.

c) Paragraph 6

Claims 23, 29-31, 34-37, and 39 as being unpatentable over Smedley and Peyman and further in view of Wong (6,692,759) as applied to claims 23, 29-30, 36, and over the combination of Smedley, Peyman, and Bardenstein further in view of Wong as applied to claims 31, 34-35, 37, and 39. This rejection does not appear to be proper as the office action alleges that claims 23, 29-31, 34-37, and 39 are rejected in view of the rejections to 23, 29-30, and 36, and further in view of claims 31, 34-35, 37, and 39. Applicants do not understand how this set of claims is rejected in view of itself; therefore, the Applicants invite the examiner to clarify the rejection.

i. Lack of Fact Finding

The office action rejected claims 34 and 35; however, in paragraph 6 of the office action no further explanation of why or how these claims are rejected was provided. Therefore, Applicants renew their arguments made in section (a)(i) of this office as to claims 24 and 32-34, and respectfully request that the rejections be withdrawn.

The office action further alleges that claims 36 and 37 are taught by the references of record, but the office action only lists the claims in the heading of paragraph 6. Claims 36 and 37 state, "wherein the erosion of the layers is halted when a desired intraocular pressure is reached." The office action does not provide any facts as to where any reference of record teaches claims 36 and 37. Without these facts a prima facie obviousness rejection cannot be sustained, and Applicants respectfully request that these rejections be withdrawn.

ii. Lack of Evidentiary Support for the Fact Finding

The office action alleges that Wong teaches claims 23 and 29-31. These claims state, "where the sustained release material is provided as layers." The passages cited by the office action as teaching these claims are not supported by the evidence found in Wong. The cited passages are attached below.

Composition of the delivery devices may be substantially homogeneous or heterogeneous. Thus, devices can be prepared where the center may be of one material and the surface may have one or more layers of the same or different composition. The layers may be cross-linked, of different molecular weight, density, porosity, or the like.

Combination chemotherapy (i.e. two or more chemotherapeutic drugs used in combination) is desirable in the treatment of many types of cancers. The multi-layered implants of the present invention may be particularly useful for delivering two or more substances for use in, for example, combination chemotherapy.

Neither of these passages appear to state that the device has a sustained release medium that is provided as layers. Moreover, the office action even seems to admit that these passages are not discussing a sustained release medium because the office action states, "the implant is multi-layered." Therefore, Applicants do not believe that the facts presented include evidentiary support in the references, thus, a proper *prima facie* obviousness rejection of claims 23 and 29-31 has been presented.

The office action rejected claim 39 in paragraph 6; however, the office action did not present any new facts or evidence as to how the additional references of record assist in rejecting claim 39. Therefore, Applicants renew their arguments presented in section (a)(ii) of this office action. Applicants do not believe that a proper *prima facie* obviousness rejection has been presented as to claim 39 and respectfully request that the rejection be withdrawn.

CONCLUSIONS

In view of Applicants' amendments and remarks, the Examiner's rejections are believed to be rendered moot. Accordingly, Applicants submit that the present application is in condition for allowance and requests that the Examiner pass the case to issue at the earliest convenience. Should the Examiner have any question or wish to further discuss this application, Applicant requests that the Examiner contact the undersigned at (248) 292-2920.

If for some reason Applicant has not requested a sufficient extension and/or have not paid a sufficient fee for this response and/or for the extension necessary to prevent the abandonment of this application, please consider this as a request for an extension for the required time period and/or authorization to charge our Deposit Account No. 50-1097 for any fee which may be due.

Respectfully submitted,

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